

AMENDED IN SENATE MAY 28, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 1822

Introduced by Assembly Member Bonta
(Coauthors: Assembly Members Nazarian and Waldron)

February 18, 2014

An act to amend Section 1635.1 of the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL’S DIGEST

AB 1822, as amended, Bonta. Tissue banks.

Existing federal law governs the processing, storage, and use of human tissue and human cell, tissue, or cellular- or tissue-based products (HCT/P), as specified, and imposes certain regulatory duties relating to HCT/P upon the federal Food and Drug Administration (FDA).

Existing state law requires the State Department of Public Health to license and regulate tissue banks, which process, store, or distribute human tissue for transplantation into human beings. Existing law generally requires every tissue bank operating in this state to have a current and valid tissue bank license issued or renewed by the department, but exempts certain activities from that requirement, including the storage of HCT/P by a licensed physician or podiatrist, as specified, if the products were obtained from a California licensed tissue bank, stored in strict accordance with manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner’s own patient, among other criteria.

This bill would create an additional exemption from the tissue bank licensing requirement for the storage of HCT/P regulated by the FDA, as specified, by a person who is licensed to provide health care services,

if specified circumstances apply, including that the HCT/P are obtained from a licensed tissue bank, stored in strict accordance with FDA regulations, and used for the express purpose of implantation into or application on a patient.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1635.1 of the Health and Safety Code is
2 amended to read:
3 1635.1. (a) Except as provided in subdivision (b), every tissue
4 bank operating in California on or after July 1, 1992, shall have a
5 current and valid tissue bank license issued or renewed by the
6 department pursuant to Section 1639.2 or 1639.3.
7 (b) This chapter shall not apply to any of the following:
8 (1) The collection, processing, storage, or distribution of human
9 whole blood or its derivatives by blood banks licensed pursuant
10 to Chapter 4 (commencing with Section 1600) or any person
11 exempt from licensure under that chapter.
12 (2) The collection, processing, storage, or distribution of tissue
13 for autopsy, biopsy, training, education, or for other medical or
14 scientific research or investigation, where transplantation of the
15 tissue is not intended or reasonably foreseeable.
16 (3) The collection of tissue by an individual physician and
17 surgeon from his or her patient or the implantation of tissue by an
18 individual physician and surgeon into his or her patient. This
19 exemption shall not be interpreted to apply to any processing or
20 storage of the tissue, except for the processing and storage of semen
21 by an individual physician and surgeon when the semen was
22 collected by that physician and surgeon from a semen donor or
23 obtained by that physician and surgeon from a tissue bank licensed
24 under this chapter.
25 (4) The collection, processing, storage, or distribution of fetal
26 tissue or tissue derived from a human embryo or fetus.
27 (5) The collection, processing, storage, or distribution by an
28 organ procurement organization (OPO), as defined in Section
29 486.302 of Title 42 of the Code of Federal Regulations, if the OPO,
30 at the time of collection, processing, storage, and distribution of
31 the organ, has been designated by the Secretary of Health and

Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, providing that the freeze-dried bone and dermis ~~has~~ *have* been obtained from a licensed tissue bank and ~~is~~ *are* stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines and ~~is~~ *are* used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of his or her license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device's or product's package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.

(B) Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of his or her license and practice for the purposes of direct patient care as described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device's or product's

1 package insert and any other manufacturer instructions and
2 guidelines.

3 (D) Acknowledgment by each practitioner that the medical
4 device or biologic product shall not be resold or distributed.

5 (9) The storage of an HCT/P regulated by the FDA pursuant to
6 Parts 1270 and 1271 of Title 21 of the Code of Federal Regulations
7 by a person who is licensed to provide health care services, acting
8 within the scope of the license and practicing in a lawful practice
9 setting, if all of the following apply:

10 (A) The HCT/P has been obtained from a licensed tissue bank.

11 (B) The HCT/P is stored in strict accordance with federal FDA
12 regulations and guidelines.

13 (C) The HCT/P is used for the express purpose of implantation
14 into or application on a patient, and not intended for further
15 distribution.